COFIX RX- povidone-iodine antiviral nasal spray liquid
COFIX-RX LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

CoFix -LXR N Atlantic Povidone-Iodine Sanitizer

Active Ingredient(s)

Povidone-Iodine 1.25 % Purpose: Antiviral

Purpose

Antiviral

Use

Antiviral to temporarily prevent viral infection and transmission

Warnings

Ask a doctor before use if you have
■ had nose ulcers or nose surgery ■ had a nose injury that has not healed ■ trouble urinating due to an enlarged prostate ■ heart disease ■ thyroid disease ■ high blood pressure ■ diabetes ■ shellfish allergy

Do not use

■ if allergic to iodine or inactive ingredient(s) ■ in the eyes ■ on children less than 3 years old

If pregnant or breastfeeding ask a healthcare professional before use.

Stop use and ask a doctor if symptoms persist or worsen ■ swelling, infection, rash, or fever occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ Adults and children over 6 years of age: 1 spray in each nostril not more than 3 times in any 24-hour period

■ Children under 6 years of age: consult a doctor

■ To use shake well, remove cap, spray directly up nostril quickly and firmly. Do not tilt

head backward while spraying. Wipe spray nozzle clean and secure cap following use. Do not share applicators.

Other information

protect from freezing and excessive heat ■ store at room temperature ■ may stain clothing ■ avoid contact with jewelry ■ Keep the carton for complete warning and information

Inactive ingredients

carrageenan, gellan gum, polysorbate, purified water, sodium hydroxide, vitamin D3, xylitol

Package Label - Principal Display Panel

10 mL NDC:81906-221-11

COFIX RX

povidone-iodine antiviral nasal spray liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:81906-221
Route of Administration	NASAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POVIDONE-IODINE (UNII: 85H0HZU99M) (IODINE - UNII:9679TC07X4)	IODINE	1.25 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	
GELLAN GUM (LOW ACYL) (UNII: 7593U09I4D)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
CARRAGEENAN (UNII: 5C69YCD2YJ)	
XYLITOL (UNII: VCQ006KQ1E)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81906-221-11	10 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	05/14/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	05/14/2021	

Labeler - COFIX-RX LLC (118069675)

Establishment

Name	Address	ID/FEI	Business Operations
LXR Biotech LLC		117520926	repack(81906-221) , manufacture(81906-221)

Revised: 5/2021 COFIX-RX LLC